Medicare Rx Update: July 26, 2006

CMS Releases Final 2007 Marketing Guidelines

The Centers for Medicare & Medicaid Services released the final 2007 Marketing Guidelines for Part D plans. These guidelines reflect feedback from the recent public comment period, changes in policy, clarifications in policy interpretations, as well as efforts to address issues that may surface over time.

Some key updates or clarifications of policy in these final guidelines relate to the use of persons performing marketing, how plans submit marketing materials to CMS for review, member identification card requirements (co-branding), employer/union information, value added items and services, as well as adding an addendum related to customer service call center requirements consistent with information provided in the 2007 CMS Call Letter. The Final 2007 Marketing Guidelines are here.

- Final 2007 Marketing Guidelines
  http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf

CMS Announces Availability of $150 Million in Medicaid Transformation Grant Funds...

CMS is encouraging states to apply for DRA transformation grants to look at particular areas of program operations for improved efficiency...and pharmacists may be eligible to participate through their state Medicaid program. Permissible uses of funds include, but are not limited to, methods for increasing the utilization of generic drugs through education programs and implementation of a medication risk management program as part of a drug use review program. Please see the attached documents for more information about the transformation grants (t*ransformation grants final release.pdf)* and specific information about the medication risk management program (*TransformationEncl A.pdf)*. States have until September 15, 2006 to apply for the grants.

CMS issues information on complaints about Prescription Drug Plans...

Mark B. McClellan, M.D. Ph.D., Administrator of the Centers for Medicare and Medicaid Services (CMS), released sponsor-level data on complaints received by CMS about the services provided by Medicare prescription drug plans in June 2006. "Almost all of our beneficiaries are in plans with complaint rates substantially less than one percent," Dr. McClellan said. Where plans' rates are high and improvement is not seen in the subsequent month, CMS may closely monitor the plan to determine whether enforcement actions are warranted. The full CMS press release and charts showing complaint rates by plan are here.

- Information on Complaints About Prescription Drug Plans
  http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1905

The release of these data is part of CMS' efforts to report on plan performance to help Medicare beneficiaries make decisions about prescription drug plans. CMS has previously provided information on plan call center performance for assisting beneficiaries and pharmacists, and expects to provide further information on

exceptions, appeals and other aspects of plan performance as data become available.

- Steps Taken to Improve Customer Service by Drug Plans
  http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1890

...and takes action on payment and remittance notices

Some pharmacies have complained to CMS that specific Plans are not issuing consistent payment and remittance notices, which causes a labor intensive financial reconciliation for the pharmacy. In response, CMS has recently released a letter advising Part D Sponsors to ensure PBM contractors are processing electronic remittances to pharmacies consistent with HIPAA standards. Part D Sponsors that do not employ the adopted standard in their processing of pharmacy remittances risk CMS sanction based on non-compliance with their Part D contract. In addition, both Part D Sponsors and their PBM subcontractors may be subject to investigation and enforcement action by CMS should a pharmacy make a formal HIPAA complaint. For more information, see the CMS letter to Part D sponsors (*HIPAA835warning070506.pdf*).

Diagnosis information for B/D issues now being accepted by some plans ...

CMS has stated that Plans may rely on physician information included with the prescription, such as diagnosis information or location of administration, to the same extent they rely on similar information acquired through documentation from physicians on prior authorization forms. At least one large Plan has put processes in place to accept the diagnosis phoned in by the retail pharmacist for B/D overlap drugs of concern... and we are hopeful that more will follow. These processes should assist in the accurate identification of drugs as B or D, while limiting the number of prior authorizations for physicians. Please click here for our clarification of plan due diligence in prior authorization of Part B versus Part D coverage determinations.

- Clarification of Plan Due Diligence in Prior Authorization of Part B Versus Part D Coverage Determinations
  http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/DueDiligenceQA_03.24.06.pdf

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Office of External Affairs

MEDICAID NEWS

FOR IMMEDIATE RELEASE
July 25, 2006

Contact: CMS Public Affairs
(202) 690-6145

CMS TO FUND STATE PLANS FOR TRANSFORMING MEDICAID TO INCREASE QUALITY AND LOWER COSTS

States will receive $150 million over 2007 and 2008 to fund research and design of ways to transform their Medicaid systems, to increase the quality and efficiency of care, Mark B. McClellan, M.D., Ph.D., administrator of the Centers for Medicare & Medicaid Services announced today.

"These transformation grants express the core goal of the DRA to give states the kind of flexibility they need to deliver high quality care in an efficient and more economical way," said Dr. McClellan. "With these grants states can streamline and modernize their systems, stabilize the growth of the program, and protect it into the future."

Funds for the Medicaid "transformation grants" were authorized by the Deficit Reduction Act of 2005 (DRA) and are aimed at state adoption of innovative systems to get more value out of the money they spend providing healthcare to their citizens who are low-income elderly, children and people with disabilities.

"Working together with the states, we've identified many ways in which Medicaid coverage can be provided more effectively, keeping costs down while providing needed coverage for more people," added Dr. McClellan. "We want to build on the steps to make Medicaid a truly sustainable program, one that can help lead the way to a more affordable, high-quality health care system for all Americans."

In fact, Medicaid spending projections are down $224 billion from earlier estimates of costs from 2006-2015—a reduction of 8 percent. The slowdown has resulted from many steps including innovative waivers, greater collaboration between states and the federal government and shifting rug costs for the dually-eligible to the new Medicare drug benefit. Greater use of community-based long-term care services and increased flexibility afforded by the Deficit Reduction Act of 2005 will lead to further efficiencies and slower growth for the future of this vital program.

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CMS is encouraging states to look at particular areas of program operations for improved efficiency, including methods for:

- Reducing patient error rates (electronic health records, clinical decision support tools or e-prescribing programs).
- Improving rates of collection from estates of amounts owed under Medicaid.
- Reducing waste, fraud, and abuse under Medicaid, such as reducing improper payment rates.
- Reducing Medicaid expenditures for covered outpatient drugs, particularly in the categories of greatest drug utilization, by increasing the utilization of generic drugs through education programs and other incentives
- Improving coordination of care through care management programs and other steps to prevent complications and duplicative or unnecessary services
- Implementation of performance-based payment programs to provide rewards and support for high-quality care
- Implementation of programs to promote personal control over services, with greater emphasis on prevention steps
- Improving access to primary and specialty physician care for the uninsured using integrated university-based hospital and clinic systems.
- Implementation of a medication risk management program as part of a drug use review program

While the DRA set aside $75 million for each of 2007 and 2008, the grant fund solicitation will be for both years at one time. All states will be eligible for a grant and grant amounts will be variable dependent upon the number of states that apply.

No state matching funds are required for these special grants. States must submit applications by September 15, 2006. More information on the grants and how state Medicaid agencies can apply for them is on the CMS Web site at: www.cms.hhs.gov/MedicaidTransGrants

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Enclosure A

Medication Risk Management Program Definition

For purposes of this grant program, a medication risk-management program means a program for targeted beneficiaries that ensures that covered outpatient drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events. Such a program may include the following elements:

- The use of established principles and standards for drug utilization review and best practices to analyze prescription drug claims of targeted beneficiaries and identify outlier physicians;
- On an ongoing basis, provide outlier physicians: a comprehensive pharmacy history for each targeted beneficiary under their care; information regarding the frequency and cost of relapses and hospitalizations of targeted beneficiaries under the physician's care; applicable best practice guidelines, and empirical references; and
- Monitoring of outlier physician's prescribing, such as failure to refill, dosage strengths, and provide incentives and information to encourage the adoption of best clinical practices.

The term "targeted beneficiaries" in the above description means Medicaid-eligible beneficiaries who are identified as having high prescription drug costs and medical costs, such as individuals with behavioral disorders or multiple chronic diseases who are taking multiple medications.

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR BENEFICIARY CHOICES

July 6, 2006

From: Cynthia G. Tudor, Director, Medicare Drug Benefit Group
To: Medicare Compliance Officer
Cc: Medicare Coordinator; General Contact; Part D Account Manager
Subject: Non-compliance with HIPAA Transaction Standard 835

Recently, a number of pharmacies have notified the Centers for Medicare & Medicaid Services (CMS) that the pharmacy benefit manager (PBM) that our records indicate you have contracted with to assist in administering your Part D benefit plan(s), *[INSERT NAME OF PBM]*, is not complying with the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In particular, the PBM is not issuing payment and remittance notices consistent with the HIPAA-adopted ACS X12N 835, Version 4010/4010A1: Health Care Claim Payment and Remittance Advice Implementation Guide ("835").

HIPAA requires the Department of Health and Human Services (HHS) to adopt standards for electronic transactions and implementation specifications for those transactions, and standard codes to be used in the transactions. In implementing the statute, HHS adopted the ASC X12N 835 standard for health care payment and remittance advice. All covered entities under HIPAA are required to use the 835 standards for their electronic payment /remittance advice transactions.

Part D Sponsors that are "covered entities" under HIPAA are required to comply with all the applicable requirements of that statute. Also, the Part D regulations at 42 CFR § 423.505(h)(2) specifically require Part D Sponsors to comply with the HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164. Your organization is accountable for your PBM's compliance with these rules consistent with the regulations at 42 CFR § 423.505(i).

CMS advises Part D Sponsors to ensure that your PBM contractors are processing electronic remittances to pharmacies consistent with the 835 standard. Part D Sponsors that do not employ the 835 standard in their processing of pharmacy remittances risk CMS sanction based on non-compliance with their Part D contract. Also, your organization and/or your PBM subcontractor may be subject to investigation and enforcement action by the CMS Office of E-Health Standards and Services should a pharmacy make a formal HIPAA complaint related to the 835 standards or other HIPAA-related matters.

CMS urges that you take steps immediately to ensure your organization's and your

subcontractor's compliance with all HIPAA Administrative Simplification Provisions. **No later than July 21, 2006, your organization must send an email to drugbenefitimpl@cms.hhs.gov specifying a date by which your PBM will be in compliance with the 835 standards.** The subject line of the email must state "HIPAA 835" and the body of the email must include all contract numbers to which your response applies. If you believe you have received this notice in error because your PBM is currently in compliance, please provide this explanation in your response. If you have any questions about this matter, please contact your Part D Account Manager.